K063389

Pride Mobility Products Corp.

Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

NOV 17 2006

Exhibit 1

510(k) Summary
Pride Mobility Products Corporation
Go Go Elite Traveller Plus, Four Wheel Scooter

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Thomas Schappert
Official Correspondent

Date Prepared:
10-18-06

Name of Device and Proprietary Name:
Go Go Elite Traveller Plus, Four Wheel Scooter / Pride Mobility Products Corporation

Common or Usual Name:
Four-Wheel Power Scooter

Classification Name:
Physical Medicine / Motorized Three - Wheeled Vehicle

Product Code:
INI

Comparison to Predicate Devices:
The Go Go Elite Traveller Plus, Four Wheel Scooter is substantially equivalent to the Pride Mobility Sunrunner SC-440 (K930953) when comparing components, performance, maneuverability, stability, and structure. The performance characteristics and the position of the electronics and drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. The differences between The Sunrunner SC-440 (K930953) and the Go Go Elite Traveller Plus, Four Wheel Scooter is in the overall size, front and rear frame construction, and the Control Mechanisms.

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Device Description:

The Go Go Elite Traveller Plus, Four Wheel Scooter is a compact battery-operated scooter having a programmable 45-amp "S" Drive Controller. Features include a removable molded plastic seat, a foldable tiller, and an off board charger. Additional safety features include electronic regenerative and electromechanical disc brakes, and rear anti-tip wheels. The Go Go Elite Traveller Plus, Four Wheel Scooter is designed for, but not limited to Pride Mobility Products Corp. providers / retailers and their consumers.

The Go Go Elite Traveller Plus, Four Wheel Scooter is designed with ultimate safety, stability, performance, and portability in mind. The main feature of the Scooter is that it can be disassembled into 4 parts: the rear section, the front section, the battery pack, and the seat. This allows for ease of use when traveling or storing the unit.

Intended Use:

The intended use of the Pride Mobility Products Corp. Go Go Elite Traveller Plus Four Wheel Scooter, is to provide mobility to persons having limited walking capabilities. The compact design and ease of assembly and disassembly, also provides a mobility product that transports easily for travel usage.

Non-Clinical Testing:

Compliance to applicable Testing Standards is as follows:

ANSI/RESNA WC Vol. 1-1998 Requirements and Test Methods for Wheelchairs (Including Scooters)

ANSI/RESNA WC Vol. 2-1998 Additional Requirements for Wheelchairs (Including Scooters) with Electrical Systems

ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.

IEC 601-1-1 Medical Electrical Equipment, General Requirements for Safety

CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The Go Go Elite Traveller Plus, Four Wheel Scooter has the same intended use and similar technological characteristics as the Sunrunner SC-440 (K930953), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Go Go Elite Traveller Plus, Four Wheel Scooter is substantially equivalent to the predicate device, has passed all the necessary testing procedures, and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2006

Pride Mobility Products Corporation
% Mr. Thomas Schappert
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

Re: K063389
Trade/Device Name: Go Go Elite Traveller Plus/Four Wheel Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: ITI
Dated: October 18, 2006
Received: November 2, 2006

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K063389

Device Name: Go Go Elite Traveller Plus / Four Wheel Scooter

Indications for Use:

The intended use of the Pride Mobility Products Corporation Go Go Elite Traveller Plus, Four Wheel Scooter, is to provide mobility to persons having limited walking capabilities. The compact design and ease of assembly and disassembly, also provides a mobility product that transports easily for travel usage.

Prescription Use X **AND / OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063389